



THE INSTITUTE FOR
REPRODUCTIVE MEDICINE
AND SCIENCE OF SAINT BARNABAS

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A Division of the Department of
Obstetrics and Gynecology at
Saint Barnabas Medical Center

94 Old Short Hills Road
East Wing - Suite 403
Livingston, New Jersey 07039
973-322-8286
Fax 973-322-8890

David Sable, M.D.
Director,
Reproductive Endocrinology & Infertility

December 29, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5360 Fishers Lane Room 1061
Rockville, MD 20852

RE: Docket#97N-484S
Suitability Determination for Donors of Human Cellular and Tissue-Based Products

To the FDA:

As physicians caring for infertile patients at the Institute for Reproductive Medicine and Science of Saint Barnabas, we wish to protest the implementation of a six month quarantine for embryos created via oocyte donation proposed in the Federal Register on September 30, 1999 under "Suitability Determination for Donors of Human Cellular and Tissue-Based Products"

Oocyte donation has made conception possible for tens of thousands of infertile couples. Given that there are no reported cases of HIV transmission via donor egg or via any in vitro fertilization technology the increased costs of implementing this policy (increased costs of cryopreservation, increased anxiety for patients, decreased success rates and increased embryo loss) make the quarantine an unnecessary obstacle thrown in the path of couples stricken with infertility.

We suggest that this proposal be withdrawn until there is scientific support for reexamining this issue.

Sincerely,

David B. Sable, M.D.

Margaret Garrisi, M.D.

Serena H. Chen, M.D.

97N 484S

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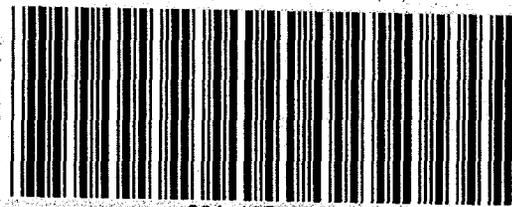
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